

**K002612 BARDEX I.C.PLUS FOLEY CATHETER WITH SILVER SALTS IN HYDROGEL COATING, MODEL 3CC BALLOON: 17008,170010,5CC BALLOON**Sep 3, 2002  
743 days to decisionK002612 · Product code: **EZL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k002612/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Aug 21, 2000
Decision date	Sep 3, 2002
Days to decision	743 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>C.R. Bard, Inc.</b>
Location	Covington, GA, US
Contact	GEORGIA C ABERNATHY
Website	<a href="https://www.bd.com">https://www.bd.com</a>
510(k) history	645 submissions · 609 cleared · 1976-2026

C.R. Bard, Inc. is a developer, manufacturer, and marketer of medical technologies headquartered in Covington, US. The company specializes in vascular medicine, urology, oncology, and surgical specialty devices. C.R. Bard maintains a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions spanning 1976 to 2026. The company's portfolio encompasses cardiovascular devices, gastroenterology and urology products, and general surgical technologies. Recent clearances include temporary pacing electrode catheters, thrombectomy systems, and ...

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